Claims

1. Isolated PM-1 protein comprising an amino acid sequence shown in the Sequence Listing, or an antigenic fragment thereof.

2. PM-1 protein or an antigenic fragment of claim 1, produced by recombinant DNA techniques.

3. PM-1 protein of claim 1 further comprising additional amino acid residues attached to either the amino terminus, the carboxy terminus or both the amino terminus and carboxy terminus of the PM-1 protein.

4. PM-1 protein of claim 3 wherein the additional amino acid residues are derived from the PM-1 protein.

5. An antigenic fragment of claim 1 which comprises a T cell epitope.

6. An antigenic fragment of claim 1 which forms a complex with a MHC II glycoprotein, which complex fails to react with the T-cell receptor.

7. A modified PM-1 protein or modified antigenic fragment of claim 1.

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8. Isolated nucleic acid encoding the PM-1 protein or antigenic fragment of claim 1, or the functional equivalent of said nucleic acid.

9. Nucleic acid of claim 8, which is DNA.

10. An expression vector containing nucleic acid encoding the PM-1 protein or antigenic fragment of claim 1, or the functional equivalent of said nucleic acid.

11. A host cell transformed with the vector of claim 10.

12. An expression vector of claim 10, wherein the nucleic acid is DNA.

13. Monoclonal or polyclonal antibodies or immunoreactive fragments thereof specifically reactive with the PM-1 protein or antigenic fragment of claim 1.

14. A therapeutic composition comprising a pharmaceutically acceptable carrier or diluent and the PM-1 protein or at least one antigenic fragment of claim 1.

15. A method of preventing the progression of Type I diabetes in an individual or preventing the development of Type I diabetes in an individual at risk of developing Type I diabetes, comprising administering to the individual an amount of the composition of claim 14 effective to prevent such progression or development in the individual.

16. A method of preventing the progression of Type I diabetes in an individual or preventing the development of Type I diabetes in an individual at risk of developing Type I diabetes, comprising administering to the individual the PM-1 protein or antigenic fragment of claim 1, in soluble and non-immunogenic form, in an amount effective to tolerize the individual to the PM-1 protein.

17. A method of claim 16 wherein T cells of the individual that would respond are tolerized to the PM-1 protein.

18. A method of treating an autoimmune disease in an individual comprising administering to the individual a therapeutic composition comprising a pharmaceutically acceptable carrier or diluent and an amino acid sequence comprising

Phe-Asp-Lys-Leu-Lys-Xaa_1-Xaa_2-Val,

wherein Xaa, is Met or His and Xaa_2 is Asp or Leu, in an amount effective to treat the autoimmune disease in the individual.

19. A method of claim 18 wherein the autoimmune disease is Type I diabetes.

20. A method of treating an autoimmune disease in an individual comprising administering to the individual a therapeutic composition comprising a pharmaceutically acceptable carrier or diluent and an amino acid sequence comprising

Xaa_3-Xaa_4-Gly-Ala-Cys-Leu-Xaa_5-Pro,

wherein Xaa_3, is Glu or Asp, Xaa_4 is Glu or Lys, and Xaa_5 is Glu or Leu, in an amount effective to treat the autoimmune disease in the individual.

21. A method of claim 20 wherein the autoimmune disease is Type I diabetes.

22. A method of detecting antibodies against PM-1 protein in a biological fluid to identify an individual at risk of developing diabetes, comprising:

a. contacting PM-1 protein comprising an amino acid sequence shown in the Sequence Listing, or an immunoreactive portion thereof, with a biological fluid of the individual under conditions which allow formation of complexes between the PM-1 protein and antibodies against PM-1 protein in the biological fluid; and

b. detecting the formation of complexes as an indication of the presence of antibody against PM-1 protein in the biological fluid and identifying the individual as at risk of developing diabetes.

23. A method of claim 22, wherein the biological fluid is human serum or plasma.

24. A method of claim 22, wherein the PM-1 protein is produced by recombinant DNA techniques.

25. A method of detecting antibody against PM-1 protein in a biological fluid to identify an individual at risk of developing diabetes, comprising the steps of:

a. providing a solid phase support to which is attached PM-1 protein comprising an amino acid sequence shown in the Sequence Listing, or a portion thereof, immunoreactive with antibody against PM-1 protein;

b. incubating the solid phase support with a sample of the biological fluid to be tested under conditions which allow antibody in the sample to bind to PM-1 protein attached to the solid phase support;

c. separating the solid phase support from the sample; and

d. determining the antibody bound to the solid phase support as an indication of the presence of antibody against PM-1 protein in the biological fluid and identifying the individual as at risk of developing diabetes.

26. A method of claim 25, wherein the PM-1 protein attached to the solid phase support is produced by recombinant DNA techniques.

27. A method of claim 25, wherein the biological fluid is human serum or plasma.

28. A method of claim 25, wherein the step of determining the antibody bound to the solid phase comprises:

a. incubating the solid phase support with a labeled antibody against immunoglobulin of the species from which the biological fluid is derived;

b. separating the solid phase support from the labeled antibody; and

c. detecting the label associated with the solid phase support as an indication of antibody against PM-1 protein in the biological fluid.

29. A method of claim 28, wherein the labeled antibody is labeled antihuman IgG antibody.

30. A kit for detecting antibody against PM-1 protein in a biological fluid comprising, in separate containers, the components:

a. a solid phase support to which is attached PM-1 protein comprising an amino acid sequence shown in the Sequence Listing, or a portion thereof, immunoreactive with antibody against PM-1 protein; and

b. a labeled anti-(human IgG) antibody.

31. A kit of claim 30, wherein the PM-1 protein attached to the solid phase support is produced by recombinant DNA techniques.

32. A method of detecting antibodies against PM-1 protein in a biological fluid to identify an individual at risk of developing diabetes, comprising:

a. contacting a modified PM-1 protein having an amino acid sequence sufficiently duplicative of the amino acid sequence shown in the Sequence Listing so that it is sufficiently immunoreactive with autoantibody against the PM-1 protein, with a biological fluid of the individual under conditions which allow formation of complexes between the modified PM-1 protein and antibodies against PM-1 protein in the biological fluid; and

b. detecting the formation of complexes as an indication of the presence of antibody against PM-1 protein in the biological fluid and identifying the individual as at risk of developing diabetes.

33. A method of tolerizing an individual exhibiting an immune response against PM-1 protein comprising administering to the individual the PM-1 protein or antigenic fragment of claim 1, in soluble and non-immunogenic form, in an amount effective to tolerize the individual to the PM-1 protein.

34. PM-1 protein having a molecular weight of about 69 kD as determined by sodium dodecyl sulfate-polyacrylamide gel electrophoresis, said protein expressed by human pancreatic islet cells, a human insulinoma, and neural cells.

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